**Study Title:**

**UC Protocol Number:**

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| **Relying Institution:** |  |

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| **Site PI Name:** |  |
| **Site PI Credentials:** |  |
| **Site PI Title:** |  |

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| **Relying Study Team Member who can answer questions regarding this site’s role in the research:** |  |
| **Team Member Phone Number/email:** |  |

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| **Site Role** | Will your site complete all activities as described in the protocol  No  Yes  If no, please describe the activities that will be completed at your site: |

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| **Financial**  **Conflict of Interest:** | The PI and research team members are responsible for reporting any personal financial conflicts of interest as defined by applicable federal regulations and any Relying Institution requirements. |

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| **Data and Specimen Storage:** | How will information/data and samples be stored for this study?   * Include paper records, electronic records and any specimens. |
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| **Recruitment**  **Methods:** | Based on the approved protocol, check all materials/methods that will be used in recruiting participants. Provide copies of any advertisements, recruitment documents or scripts to the UC Lead Study Team to be submitted to the UC BSD IRB. If you would like to use materials not described in the protocol or approved by the Reviewing IRB, please contact the UC study team before submitting the requested materials. |
| Existing Information from medical records  Existing Information from database, registry, or previous study  Advertisements  Posters  Brochures  E-mail  Letter  Telephone script  News releases  Pictures/diagrams/models  Group Presentation  Other: Describe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Consent**  **Materials:** | Based on the protocol, please check all materials that will be used to obtain and document consent. If your site would like to propose a consent method not approved by the Reviewing IRB, you will need to contact the Lead Study team before submitting. |
| Consent Document  Letter or Information sheet containing elements of consent  Assent Document  Verbal/Phone Script  Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | |

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| **Consent Process:** | Provide a step-by-step description of the enrollment and consent process for participants   * Describe each study population separately including control population * Describe who will be conducting the consent process * Include when recruitment and consent materials are used * Use THIRD person active voice. For example, "the principal investigator will identify potential participants, the study coordinator will discuss the study with participants over the telephone and schedule the first study visit, etc..." * Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process |
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| **Protocol Specific**  **Training:** | Describe how study team members are trained for their role on this protocol. For example, will there be a site initiation visit or similar? |
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| **Relying Site Principal Investigator Attestation and Signature**  On behalf of the participating site, I confirm that the information provided is accurately reflected in this document. By signing the below, I additionally agree to the following: | |
| I agree to conduct the study in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the overall study/lead UChicago PI, except when necessary to protect the safety, rights, or welfare of subjects.  I agree to personally conduct or supervise the described research as conducted at this relying site.  I agree to inform (as applicable) any potential subject, or any persons used as controls, what activities are research activities and/or standard of care procedures.  I will ensure that the requirements relating to obtaining informed consent approved by the UChicago BSD IRB are followed, as applicable.  I agree to follow UChicago BSD IRB requirements to report promptly reportable events to the overall study/lead UChicago BSD IRB that occur in the course of the research.  I have read and understand the research protocol, including the potential risks of the research.  I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study at the participating site are informed about their obligations in meeting the above commitments.  I agree to maintain adequate and accurate records in accordance with regulatory requirements and to make those records available for inspection by regulatory oversight agencies, including the University of Chicago.  I agree to provide participating site information, including the progress report to the overall study/lead UChicago BSD IRB in a timely manner to comply with continuing review requirements (if applicable) and any other requests related to IRB oversight of the multi-site research.  I agree to promptly report to the overall study/lead UChicago PI all changes in the research activity and all unanticipated problems involving risks to human research participants or others, which would be communicated to the UChicago BSD IRB.  I confirm the work proposed does not involve any data, materials, drugs or devices from a company in which any local members of the study team have a financial interest, or in the case of a corporate sponsor, I have not received any payments, stock or equity from this sponsor in the past 2 years. If any members of the research team have a financial interest, this has been appropriately disclosed and applicable management plan has been provided.  I will not make any changes in the research without prospective UChicago BSD IRB approval, except where necessary to eliminate apparent immediate hazards to human research participants.  I agree to comply with all other requirements regarding the obligations of principal investigators as a participating site PI and all other pertinent requirements that I must adhere to, including local state laws.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Relying Site Principal Investigator Signature Date |